REMARKS

I. Status of the claims and Support for Amendment

Claims 31 and 41 are amended.

Claims 42-44 are cancelled.

Claims 45-49 are added.

Claims 31, 37, 41, and 45-47 are currently pending.

With reference to the published specification in US 2003/0039954 A1:

Support for new claim 45 is found on p. 14, ¶¶ 231-34.

Support for new claim 46 is found on p. 9, ¶ 147.

Support for new claim 47 is found on p. 11, ¶ 186.

II. Rejection under 35 U.S.C. § 112

A. Written Description

Claims 31, and 41-43 are rejected under 35 U.S.C. § 112, ¶ 1 as allegedly containing subject matter that was not described in the specification. Specifically, the rejection recites:

> [the] claims are directed to encompass the vast genus of probes that specifically hybridize to genomic RNA (or any species of RNA) of the HIV-3 retrovirus deposited at the European Collection of Animal Cell Cultures (ECACC) under No. V88060301. This vast genus fails to meet the written description provision of 35 USC 112, first paragraph.

In response to the Examiner's rejection, the Applicant has amended claims 31 and 41, and has cancelled claims 42 and 43.

Currently amended claim 41 now describes hybridization using a "*DNA probe that comprises a sequence that is identical to all or a portion of the cDNA corresponding to the entire RNA of the HIV-3 retrovirus deposited at the European Collection of Animal Cell Cultures (ECACC) under No. V88060301.*" Applicant provides adequate disclosure of the relevant starting material through deposit

at the European Collection of Animal Cell Cultures (ECACC) under No. V88060301. *Enzo Biochem., Inc. v. Gen-Probe, Inc.*, 296 F.3d at 1325 ("Reference in the specification to a deposit in a public depository, which makes its contents accessible to the public when it is not otherwise available in written form, constitutes an adequate description of the deposited material sufficient to comply with the written description requirement of §112, ¶1."). As a result, deposit of the HIV-3 strain shows that Applicant was in "possession of the invention" as required under *Vas-Cath v. Mahurkar*, 19 USPQ2d 1111, the relevant authority cited by the Examiner.

The examiner also argued that "while SEQ ID NO:1 is disclosed, the specification is silent as to whether said sequence will meet the functional limitations of the rejected claims." (Office Action, p. 5). In support of the contrary, Applicant directs the Examiner's attention to the following excerpts from the 2003/0039954 A1 specification: page 11, ¶¶ 197-99 and page 14, ¶¶ 231-34 (and figures referenced therein). In those excerpts, Applicant discloses using the 70-11 probe (sequenced and named as SEQ ID NO:1) for hybridization with ANT 70. ANT 70 is the HIV-3 strain deposited at the ECACC (US 2003/0039954 A1, Specification, p.2 ¶13). Figure 14 shows that the probe comprising SEQ ID NO:1 successfully hybridized–that is, detected–the claimed HIV-3 strain.

Accordingly, Applicant believes the rejections of claims 31, 37, and 41 for lack of adequate written description has been overcome and may now properly be withdrawn.

B. Enablement

Claims 31, 37, and 41-43 are rejected under 35 U.S.C. § 112, first paragraph as allegedly not being enabled. Point one of the rejection states that in regard to the term "stringent conditions," the recitation of only one possibility is not sufficiently limiting in light of the use of open claim language in claim 41. Applicant in no way concedes that those skilled in the art would not understand that the original disclosure serves as a well-defined reference point for the relative stringency disclosed in the claim limitations; particularly in regard to: the disclosed ionic strength (SSC concentration),

detergent concentration (SDS), temperature, hybridization accelerant (dextran sulfate) and components to inhibit non-specific hybridization (milk powder). In light of examiners comments, however, Applicant has amended the claims to recite conditions that "consist essentially of" the disclosed parameters. Applicant contends that the Examiner's second point that "recitation of specific hybridization conditions is insufficient to provide enablement" is also rectified by this claim amendment. The specific disclosure of the hybridization and wash conditions explicitly enables one of ordinary skill in the art to perform the claimed process. (See US 2003/0039954 A1, p.11 ¶¶ 199, 231). This amendment adequately addresses Examiner's concerns and should no longer be cause for rejection.

Examiner's further argues that "[c]laims 31, and 41-43 encompass polynucleotides (DNA probes) comprising non-disclosed nucleic acid sequences that **hybridize** to the genomic RNA of HIV-3 retrovirus deposited at the [ECACC] under stringent conditions." (Office Action, p. 7). As discussed above, claim 41 has been amended to recite that the claimed probes are derived from the sequence of DNA deposited at the ECACC. Further, examiner comments that "[c]laims 37 and 44 are drawn to DNA probes comprising SEQ ID NO:1 or the complement of SEQ ID NO:1. Applicant agrees, but does not agree that "the specification does not teach how to make any polynucleotides that specifically hybridizes to the genomic RNA of HIV-3 retrovirus deposited at the [ECACC]" and further addresses this point.

Applicant discloses a precise, step-by-step method for making and using the HIV-3-derived probes using standard methods in the art and commercially-available reagents. (*See* US 2003/0039954 A1, Specification, p. 11, ¶¶ 184-99). From the disclosure provided, a person skilled in the relevant art would have little difficulty in creating probes from the virus deposited at the ECACC: purifying the template RNA from viral culture (¶ 185); preparing a radiolabeled cDNA complement from the purified RNA using standard reverse transcriptase PCR technology (¶ 186, sent. 1-4); preparing the ends of the radiolabeled cDNA complement for cloning and purifying them via

agarose-gel purification (¶ 186, sent. 5-6); excising (recovering) 500-2000 base pair purified fragments and ligating them into a pre-treated plasmid vector (¶ 186, sent. 7); transforming bacteria with said cloned DNA and selecting colonies of properly transformed bacterial via *in situ* hybridization and autoradiography (¶ 186, sent. 7; ¶ 187-191); isolating the plasmid DNA from bacterial cultures propagated from those described in ¶ 186, sent. 8; analyzing the inserts from the isolated DNA via agarose gel electrophoresis (¶ 194, sent. 2); and sequencing the insert by the Sanger dideoxynucleotide sequencing method (¶¶ 195-96). Applicant also provides a detailed method (including reagent concentrations and incubation times used in the specified protocols where experimental variability may result) for testing the HIV-3 derived probes for their intended purpose—to hybridize to the HIV-3 RNA deposited at the ECACC under specified conditions (*See* ¶¶ 197-98, 231)). There should be no mistake that SEQ ID NO:1 is one example of a probe that was created by the disclosed protocol and that it ably performs in the claimed method (*See* US 2003/0039954 A1, Results, page 14, ¶¶ 231-34 (and fig. 14 referenced therein)).

The disclosed protocol and the identity of SEQ ID NO:1 is sufficient to overcome the requirements for making the claimed probes via the claimed process. Chapter 2100 of the MPEP states: "As long as the specification discloses at least one method for making and using the claimed invention that bears a reasonable correlation to the entire scope of the claim, then the enablement requirement of 35 U.S.C. 112 is satisfied." MPEP § 2164.01(b) (*citing In re Fisher*, 427 F.2d 833, 839 (CCPA 1970)). As described in detail above, the method for making the cDNA probes is disclosed and the success of using that process is evidenced by the disclosure of SEQ ID NO:1.

New claim 47 is also enabled by the specification. Like the probe identified as SEQ ID NO:1, other probes created by the claimed method are also disclosed in the specification. Specifically, support for claim 47 can be found on page 11 ¶ 194 of the specification. The specification describes detection of seventeen bacterial colonies that had been transformed with DNA derived from HIV-3 deposited at the ECACC. As the specification states, five of these inserts

selected for further analysis and ranged in size from 800–1600 nucleotide base pairs. SEQ ID NO:1 was the determined from the longest of these inserts (See US 2003/0039954 A1, p. 11 ¶ 198). A skilled artisan would know that the other disclosed probes could be characterized in the same way as the SEQ ID NO:1 exemplar. Therefore, claim 47 is sufficiently enabled.

New claim 46 is also adequately disclosed on page 9 ¶ 147 and page 14 ¶¶ 227-29. The excerpt on page 9 particularly discloses the use of probes derived from the conserved structural genes from HIV. The disclosure in the referenced section of page 14 describes using HIV-1 and HIV-2 derived probes corresponding to the *gag* and *pol* genes (from HIV-1) and the *env* gene (from HIV-2). Under stringent conditions (as defined in the published specification at page 11 ¶ 199) there was no cross-reactivity observed between the disclosed probes from these highly conserved genes. A skilled artisan, thus, would know that the sequences encoding the HIV-3 enzymes would be beneficial for differential detection of the HIV-3 variant deposited at the ECACC. A skilled artisan would also know that probes derived from the well-characterized gene sequences from HIV-1 and HIV-2 could be used in nonstringent hybridization (see US 2003/0039954 A1, p. 11 ¶ 192) to identify the HIV-3 target sequences. Accordingly, one of ordinary skill would be enabled to easily identify the sequences of the claimed genes. Therefore, Claim 46 is enabled.

In regard to Examiner's rejections based on composition of the potential probes generated by the claimed method, Applicant respectfully traverses. As described in the specification, one of ordinary skill in the art would know that the probes are for differential detection of the HIV-3 virus, specifically for epidemiological studies (*See* US 2003/0039954 A1, pp. 14 ¶ 231, 15-16). To that end, Examiner's argument that the probes may "read[] on intact genomic material comprising enhancers, promoters, introns, and splice cites" is of little or no consequence. Probes generated by the claimed method to hybridize to such regions would still be useful for differential detection of the HIV-3 variant. Of course, the probes that may be obtained from the disclosed protocol may or may

not share structural or functional properties with SEQ ID NO:1. As the protocol is designed to result in a population of selectable probes, the variability is not only expected, but also desired.

Finally, Examiner argues that "the specification is silent as how one would detect a non-genomic RNA species using a probe that hybridizes to genomic RNA". In response, claims 31 and 41 have been amended to claim all RNA within the deposited virus. The ability to distinguish between genomic RNA and any other non-genomic DNA is not requisite for the claimed invention.

In light of the claim 41 amendments and the foregoing responses, Applicant believes the rejections of claims 31, 37, and 41 for lack of enablement has been overcome and may now properly be withdrawn.

C. **New Matter and Indefiniteness**

Claims 42–44 have been withdrawn. Examiner's "new matter" and "indefinite" rejections of claims 42–44 based on 35 U.S.C. § 112, ¶ 1 for the claim language, "stringent conditions comprise conditions at least as stringent as . . ." is now moot and may now properly be withdrawn.

III. Rejection under 35 U.S.C. § 102

Claims 42 and 43 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Montagnier *et al.* (WO 86/02383). Claims 42 and 43 have been withdrawn, therefore, as to those claims Examiner' rejection is now moot and may properly be withdrawn. Claim 41, however, has been amended to include matter formerly contained in claims 42 and 43. Applicant respectfully traverses.

Chapter 2100 of the *MPEP* states that "'[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.' *Verdegaal Bros. V. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2D 1051, 1053 (Fed. Cir. 1987)." *MPEP* § 2131.

As described above, the claims now specifically recite the stringent hybridization and wash conditions to be used in the claimed process. Montagnier *et al.* does not describe such conditions, either expressly or inherently. Accordingly, Montagnier *et al.* does not anticipate the currently pending claims. Therefore, the rejection under 35 U.S.C. § 102(b) may now properly be withdrawn.

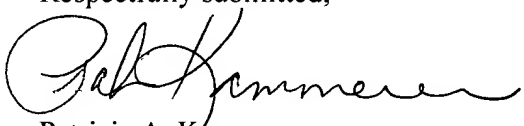
IV. Conclusions

In view of the foregoing Amendments and Remarks, Applicant believes that all rejections of the pending claims have been addressed and overcome. Accordingly, Applicant respectfully requests favorable reconsideration of the case and issuance of a Notice of Allowance therefor.

Should any additional fees under 37 C.F.R. §§ 1.16 to 1.21 be required for any reason relating to the enclosed materials, the Commissioner is authorized to deduct said fees from Deposit Account No. 01-2508/11362.0025.DVUS03.

In an effort to facilitate progression to grant, the Examiner is invited to contact the undersigned attorney at (713) 787-1438 with any questions, comments, or suggestions relating to the referenced patent application.

Respectfully submitted,



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